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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER	
SMITH, CAROLYN L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,759	SHAPIRO, PHYLLIS	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-16 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 7/22/04, are acknowledged. Amended claims 9, 15, and 16 are acknowledged.

Applicant's arguments, filed 7/22/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3 and 5-24 are herein under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 23 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained and reiterated for reasons of record.

Claim 23 is rejected due to the claim steps lacking correspondence to the preamble of the claim. In claim 23, the claim steps only contain correction factors multiplied by plasma or serum hemoglobin values when in actuality, the preamble states a method for correcting values in blood, plasma, or serum. Thus, it is unclear whether the preamble or the correcting step in this

claim controls the metes and bounds of the claimed invention. Appropriate clarification of the metes and bounds of the claim via clearer claim wording is requested.

Applicant amended claim 16 to resolve this issue, but not claim 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made..

Claims 1-3, 5-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chupp et al. (P/N 5,631,165) in view of Chang et al. (P/N 5,200,323), Samsoondar (WO 98/39634), and Rodriguez et al. (P/N 6,228,652).

Chupp et al. teach a system where information about the blood sample is entered into the controller of an automated system that activates the analyzers to perform analyses under the direction of the controller (col. 10, lines 54-67). Chupp et al. describe the system as including an analyzer module, a data station module, and a pneumatic unit (col. 11, lines 27-29). The data station module has "sufficient software algorithms to manipulate measured data, calculate parameters and display results in a variety of formats" (col. 11, lines 62-67). Chupp et al. further

discuss the analyzer module in which sample tubes of blood are automatically transported with bar code labels that can be read with a bar code reader so that sample information can be inputted into the system controller (col. 25, lines 22-35). Chupp et al. teach correcting MCH and MCHC in blood by performing the mathematical computations described in b(1) – (2) of claim 9 where the constants to correct dimension units for formula 1 is 10 and for formula 2 is 100 (col. 53, lines 66-67 and col. 54, lines 1-26). Chupp et al. teach the use of setting hemoglobin flags if any results are abnormal or suspect (col. 61, lines 50-51) which suggests the blood sample tested may be normal or abnormal as stated in claim 3. Chupp et al. also describe anemic patients with increased reticulocyte counts as indicating rapid erythroid turnover suggesting acute blood loss or hemolysis (col. 1, lines 62-65) as stated in claims 5 and 6. However, Chupp et al. do not teach the presence of an extracellular hemoglobin product or oxygen-carrying blood substitute such as recombinant human hemoglobin, the formulas being determined by cell-by-cell measurements, or a corrected chemistry value determined via a subtraction step.

Chang et al. describe the use of modified hemoglobin blood substitutes as alternatives to human donor blood, such as recombinant human hemoglobin (col. 3, lines 61-63). Chang et al. describe adding modified hemoglobin blood substitutes to a human plasma sample with a centrifugation step (abstract) which represents isolation and purification of animal blood, as stated in instant claims 8, 11, and 18.

Samsoondar describes a method of identifying and quantifying the concentration of a blood substitute (abstract). Samsoondar describes a method of taking the measured concentration of the blood substitute and correcting for its effect on a measured analyte concentration, such as serum/plasma total protein (abstract). Samsoondar describes making the

necessary adjustment or correction to the measured analyte concentration to remove the effect of the blood substitute (page 5, lines 5-9) which represents a subtraction of the blood substitute correction factor from the original reported chemistry result, as stated in instant claim 16. Figure 3 (with the linear calibration mathematical formula) provides results of a linear regression fit of data generated from true Hb calibration (fitted Hb value) in the presence of cross-linked hemoglobin (blood substitute) and other interferents (actual Hb value) (page 5, lines 20-22) which represents a correction factor multiplied by the hemoglobin value scaled to the appropriate units of dimensions of the reported analytes to correct for interference, as stated in instant claim 16. Samsoondar describes quantifying the relationship between measured amounts of each analyte with respect to the blood substitute present in the serum or plasma specimen (page 18, lines 23-26). In an example, Samsoondar describes finding the actual serum total hemoglobin concentration by subtracting the blood substitute times the slope of the regression line (correction factor) from the measured value (page 23, lines 4-15). Samsoondar describes determining the concentration of true hemoglobin in the presence of blood substitutes (abstract). Samsoondar describes using samples contained in labeled tubes in a blood analyzer (abstract). Samsoondar describes a user can specify a particular interferent to be analyzed (page 11, lines 2-4). Samsoondar describes screening samples by taking successive sample measurements for interferents and blood substitutes (page 11, second paragraph).

Rodriguez et al. describe taking measurements on every cell where measurement data are processed to yield a report of cells and cellular hemoglobin information including mean volumes for a sample (col. 13, lines 20-33). Rodriguez et al. describe measuring cell-by-cell hemoglobin (col. 13, lines 34-42).

Chupp et al. describe the presence of classes and subclasses of red blood cells (col. 3, lines 53-54) and how the two methods used can distinguish cells and subdivide the cell types into finer classifications (col. 3, lines 7-14). Chupp et al. also discuss the need for increasing the precision and accuracy of previous manual methods of hematology analysis by using automated systems (col. 7, lines 11-16). Chang et al. point out it would be highly desirable to screen human blood and plasma to determine the safety of modified hemoglobin blood substitutes for humans (col. 4, lines 11-30). Samsoondar states that although cross-linked hemoglobin blood substitutes data are collected in his invention, it is understood that similar calibration algorithms for measuring other blood substitutes and correcting for their effects on blood test results, are within the scope of his invention (page 12, lines 12-16). One of ordinary skill in the art would have been motivated to enhance the automated hematology analyzer and method for correcting MCH and MCHC values in blood, as stated by Chupp et al., by including all types of blood samples in use at the time of the invention such as those containing modified hemoglobin blood substitutes, as stated by Chang et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use samples including recombinant human hemoglobin and other modified hemoglobin blood substitutes (as stated by Chang et al. and Samsoondar) in automated methods and systems of obtaining accurate MCH and MCHC values (as stated by Chupp et al. and Samsoondar) including the successive cell-by-cell measurements as exemplified by Rodriquez et al., because this information would enhance understanding of safety and potential problems of the various types of blood and blood substitutes in humans at the time of the invention, as stated by Chang et al. (col. 4, lines 11-30). Thus, Chupp et al., in

view of Chang et al., Samsoondar, and Rodriguez et al., motivate the limitations in claims 1-3, 5-15, 17-22, and 24 of the instant invention.

Applicant states the formulas in Chupp et al. use the term HGB (hemoglobin) while the formulas in independent claims 1, 6, 15, and 16 of the present invention use the term "cellular" hemoglobin. As the specification does not appear to have a clear and concise definition of "cellular hemoglobin", this phrase can be interpreted to be hemoglobin from a cell. As hemoglobin is well known to be "an iron-containing respiratory pigment of vertebrate red blood cells", this hemoglobin described by Chupp et al. reads on the "cellular hemoglobin" in the instant claims. Applicant states that Chupp et al. do not teach the presence of an extracellular hemoglobin product or oxygen-carrying blood substitute such as recombinant human hemoglobin or the formulas being determined by cell-by-cell measurements. It is noted that because the Chupp et al. reference does not teach all of the limitations in the claims, it is used in a 35 USC 103 (a) rejection as opposed to a 35 USC 102 rejection.

Applicant argues that claims 8, 11, and 18 have been misread regarding isolation and purification of animal blood. This statement is found unpersuasive as the claim limitations have been broadly and reasonably interpreted to include the centrifugation step described in the Chang et al. abstract. According to the online Merriam-Webster online dictionary, "centrifuge" is defined as "a machine using centrifugal force for separating substances of different densities, for removing moisture, or for simulating gravitational effects" which clearly represents an isolation and purification of animal blood. According to the online Merriam-Webster online dictionary, "separate" is defined as becoming isolated from a mixture which represents a type of purification

as well. Applicants state the Chang et al. centrifugation step is performed before the addition of the modified hemoglobin and so has no role in the purification of the hemoglobin. This statement is found unpersuasive as the method described the steps of Chang et al. comprise various steps without giving a specific order to the steps. As long as all of the steps are performed the method is complete.

Applicant states the Samsoondar reference cannot be used to interpret mean cell-by-cell measurements as serum and plasma do not contain cells. Another reference (Rodriguez et al.) has been added to address the cell-by-cell measurements and cellular hemoglobin concentration measurements.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

Ardin H. Marschel 10/27/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER

October 6, 2004